**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**WESTERN DIVISION**

**UNITED STATES EX REL,**
**DR. DONALD LYNCH**
c/o Jacobs, Kleinman, Seibel & McNally, LPA
30 Garfield Place, Suite 905
Cincinnati, Ohio 45202

Service to:
Benjamin C. Glassman
U.S. Attorney's Office
Southern District of Ohio
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202

Service to:
Jeff Sessions
Attorney General for the United States
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

Plaintiff-Relator

vs.

**UNIVERSITY OF CINCINNATI**
**MEDICAL CENTER, LLC**
3200 Burnet Avenue
Cincinnati, Ohio 45229

and

**UNIVERSITY OF CINCINNATI**
**PHYSICIANS, INC.**
**c/o Lori Mackey, Statutory Agent**
222 Piedmont Avenue, Suite 1200
Cincinnati, Ohio 45219

and

CIVIL ACTION NO: 1:18CV587

JUDGE: DLOTT

**[FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. 3720(b)(2) AND SOUTHERN DISTRICT OF OHIO CIVIL RULE 3.2]**

**COMPLAINT WITH JURY DEMAND**

**UC HEALTH, LLC**
3200 Burnet Avenue
Cincinnati, Ohio 45229

Defendants

## I. INTRODUCTION

1. This is a *qui tam* action brought by Relator Dr. Donald Lynch ("Relator"), for himself and on behalf of the United States, to recover damages and civil penalties arising from Defendants University of Cincinnati Medical Center ("UCMC"), an Ohio nonprofit corporation, University of Cincinnati Physicians, Inc. ("UCP"), an Ohio corporation, and UC Health LLC ("UC Health"), an Ohio not for profit limited liability company, for their unlawful acts which resulted in numerous violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA").

2. From December 2015 through the present, UCMC, UCP, and UC Health have knowingly submitted false claims for payment to the United States relating to medical procedures performed by their agents and identified as Transcatheter Aortic Valve Replacements ("TAVRs") that were not reasonable and necessary pursuant to 42 U.S.C. §1395y(a)(1)(A).

3. Pursuant to the FCA, the Relator, on behalf of the United States, seeks recovery of damages and civil penalties for UCMC's, UCP's, and UC Health's presentment of false and fraudulent claims for payment to the Medicare, Medicaid and TRICARE/Champus government medical benefit programs.

4. This complaint is being filed under seal and must remain under seal while the United States investigates the allegations and determines whether it will intervene in the action.

## II. JURISDICTION AND VENUE

5. This action arises under the FCA.

6. Jurisdiction over this action is vested in this Court under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331.

7. Venue is proper in this district under 31 U.S.C. § 3732(a). It is also proper because UCMC, UCP, and UC Health reside and transact business within this District, and, as part of that business, each has presented false claims for payment to the United States, and in connection with those claims, and each has received millions of dollars in payments to which they were not entitled.

8. Pursuant to 31 U.S.C. § 3730, this complaint is being filed in camera. Unless the Relator concurs in a request to extend the time-frame for intervention, the complaint will remain under seal for a period of at least 60 days until after the United States has received the complaint, material, and information required under the statute. None of the allegations in the Complaint or Disclosure Statement, are based upon any public disclosure as defined under the FCA.

## III. THE PARTIES AND RELATED ENTITIES

9. The real party in interest for the claims in this action is the United States of America.

10. Relator is a resident of the State of Ohio, and a Board Certified Interventional Cardiologist licensed to practice medicine in Ohio. Since the fall of 2015, Relator has been a physician employee of UCP and is a member of the attending medical staff for UCMC. He has first-hand knowledge of the facts alleged herein.

11. On March 28, 2018, Relator, as an "original source," voluntarily disclosed by email the information stated herein to the United States Attorney for the Southern District of Ohio pursuant to 31 U.S.C. § 3730(d)(4)(B) before filing the Complaint. Relator brings this case under 31 U.S.C. § 3730(b).

12. UCMC is a not for profit limited liability company organized under the laws of the State of Ohio with its principal place of business in Cincinnati, Hamilton County, Ohio. It is a critical care hospital. UC Health is a limited liability company organized under the laws of the State of Ohio to operate the UC Health System which, among other facilities and services, includes UCMC and UCP.

13. UCP is an Ohio corporation. It is Relator's employer. UCP employs physicians and leases those physicians and other employees to University of Cincinnati Physicians Company LLC of which UC Health is the sole member. It allegedly exists to carry out the mission of UCMC and the University of Cincinnati College of Medicine.

## IV. THE LAW

### A. The False Claims Act (31 U.S.C. §§ 3729-33)

14. The FCA provides for the award of treble damages and civil penalties against any person for, inter alia, knowingly causing the submission of false or fraudulent claims for payment to the United States Government or making or using false statements which are material to false or fraudulent claims paid by the United States.

15. Under the FCA, 31 U.S.C. §3729, a person is liable to the United States for:

(A) knowingly presenting, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

16. The standard of proof under the FCA is preponderance of the evidence. 31 U.S.C. § 3731(c).

**B. Federal Health Care Programs**

17. In 1965 Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain health care services. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A.

18. Part A of the Medicare Program authorizes payment for institutional care, including for care provided at hospitals, skilled nursing facilities, and home health care. *See* 42 U.S.C. §§ 1395c-1935i-4.

19. Part B of the Medicare Program authorizes payment for outpatient health care expenses and physician fees. These fees are administered through Medicare carriers, and payments are made through a trust fund ("the Medicare Trust Fund"). *See,* 42 U.S.C. §§ 1395j-1395w-4.

20. UCMC, UCP, and UC Health derived and continue to derive substantial revenue from the Medicare Program.

21. The Department of Health and Human Services ("HHS") has overall responsibility for the administration and supervision of the Medicare Program. The center for Medicare and Medicaid Services ("CMS") is an agency of HHS, and it is directly responsible for the administration of the Medicare Program. The responsibility for processing claims and making disbursements from the Medicare Trust Fund on behalf of the United States is delegated by CMS to certain contracted agents.

22. Payment of Part A claims made to hospitals under the Medicare Program are administered by fiscal intermediaries. In Ohio, the fiscal intermediary is National Government Services.

23. Outpatient hospital and physician claims made under the Medicare Program are paid separate and apart from hospital Part A claims, pursuant to a Medicare reimbursement schedule.

**C. Other Federally Funded Health Insurance Programs**

24. Federal health care programs also include any plan or program that provide health benefits directly or indirectly through insurance or that are otherwise funded directly in whole or in part by the United States Government. 42 U.S.C. § 1320a-7b(f)(1). These include military benefits through the TRICARE/Champus program, the Federal Employees Health Benefit Program, and other federally funded insurance (excluding federal workers compensation claims).

25. State Medical Assistance (or "Medicaid") programs are also federal health care programs. *See*, 42 U.S.C. § 1320a-7b(f)(2).

**D. Provider Agreement**

26. Medicare providers, including UCMC, UCP, and UC Health are required to enter

into provider agreements with the federal government.

27. Hospitals that meet Medicare requirements enter into provider agreements pursuant to forms CMS 1450-UB-04 and CMS-855(A). Hospitals must also reconcile payments made throughout the year by the submission of a year-end cost report identified as CMS-2552. Physicians and their corporate entities that meet Medicare requirements enter into provider agreements through the use of CMS-1500s, CMS-855(B), and CMS-855(I).

28. Under the terms of the provider agreements referred to in paragraph 27, above, a Medicare provider certifies that it will comply with all laws and regulations concerning Medicare and the FCA in connection with the claims it submits for payment relating to services provided to patients in which reimbursement is sought from a federal health care program.

**E. Legally False Claims**

29. The FCA generally prohibits private parties from knowingly submitting a false or fraudulent claim for reimbursement. 31 U.S.C. §3729(a)(1)(A).

30. False or fraudulent claims include both factually false and legally false requests for payment. *United States ex rel Polukoff v. St. Mark's Hospital,* 2018 U.S. App. LEXIS 18539, ¶19 (10th Cir. July 9, 2018).

31. Claims arising from legally false requests generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment. *United States ex rel Polukoff,* 2018 U.S. App. LEXIS 18539 at ¶20.

32. The submission of claims that do not comply with Medicare's reasonable and necessary requirement constitute legally false requests for payment. *United States ex rel Polukoff,* 2018 U.S. App. LEXIS 18539 at ¶20.

33. Claims of legal falsity can rest on one of two theories – express false certification and implied false certification. *Id.*

34. Claims for implied false certification occur when a payee, through the act of submitting a claim, knowingly and falsely implied that it was entitled to payment. *Id.* at ¶21.

35. In connection with UCMC's, UCP's, and UC Health's false claims that are the subject of this Complaint, they certified that they had complied with Medicare and the FCA and that all of the claims presented for medical services that were rendered by the parties were reasonable and necessary.

36. Certification of compliance of the reasonableness and necessity of the medical procedures for which presentment of a claim is made to the United States is a prerequisite for hospitals, physicians, and their corporate entities to obtain a government benefit such as Medicare, Medicaid, TRICARE/Champus program, and other payments from federal health care programs. An action for the presentation of claims seeking reimbursement for services and items that are medically unnecessary is viable under the FCA. *United States ex rel Polukoff,* 2018 U.S. App. LEXIS 18539 at ¶23 citing to *United States ex rel Riley v. St. Luke's Episcopal Hosp.* 355 F.3d 370, 376 (5th Cir. 2004).

37. A Medicare claim is false if it is not reimbursable and a Medicare claim is not reimbursable if the services provided were not medically necessary. For a claim to be reimbursable, it must meet the United States' definition of reasonable and necessary as found in the Medicare Program Integrity Manual. *United States ex rel Polukoff,* 2018 U.S. App. LEXIS 18539 at ¶23; Amicus Brief of the United States in *United States ex rel Polukoff, supra,* attached as Exhibit 1.

38. Accordingly, each time a claim is submitted, that claim is a separate and illegal claim that is actionable under the FCA. See, *United States ex rel Augustine v. Century Health Services*, 289 F.3d 409, 415 (6th Cir. 2002).

## V. THE DEFENDANTS' ILLEGAL SCHEME

### A. Defendants Submitted False Claims for TAVRs.

39. As indicated above, by statute, no payments may be made under Medicare for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. See 42 U.S.C. §1395y(a)(1)(A).

40. The determination of whether a medical service is reasonable and necessary has been delegated in the first instance to the Secretary of HHS. HHS decides whether to exclude payment for medical services by promulgating National Coverage Determinations ("NCD"). See 42 U.S.C. §§1395y, 1395ff(a)(1)(A), 42 CFR 405.1060(a); *United States ex rel Polukoff v. St. Mark's Hospital,* 2018 U.S. App. LEXIS 18539, ¶6 (10th Cir. July 9, 2018); *United States ex rel Ryan v. Lederman*, 2014 U.S. Dist. LEXIS 65666 at ¶3 (E.D. N.Y. May 13, 2014)

41. NCDs are national payment policies relating to the payment of covered items and services by medical providers and are binding on both Medicare contractors and administrative law judges who preside over medical coverage appeals. *United States ex rel Groat v. Boston Heart Diagnostic Group*, 255 F. Supp.3d 13, 18 (D.D.C. 2017); *Almy v. Sebeleus*, 679 F.3d 297, 299 (6th Cir. 2012). They are made through an evidentiary based process with opportunities for public participation. 78 Fed. Reg. 48164-69 (Aug. 7, 2013)

42. An NCD is a determination by the United States of whether payment a particular item or service is covered under Medicare. 42 CFR §405.1060(a)(1), 68 Fed. Reg. 187, pp.

55634, 55635 (Sept. 26, 2013). Thus, NCDs are controlling authorities for payments by Medicare contractors. 78 Fed. Reg. 152, pp. 48164, 48165 (Aug. 7, 2013).

43. An institutional provider such as UCMC or UC Health must present a claim for payment pursuant to CMS Form 1450 or UB-04. *See* 42 CFR §424.32. This form requires UCMC or UC Health to certify that it did not knowingly or recklessly misrepresent or disregard or conceal material facts to the claims submission. Additionally, UCMC or UC Health, in its Medicare Enrollment Form 855(A), certifies compliance with Medicare laws such as 42 U.S.C. §1395y(a)(1)(A). When UCMC or UC Health request reimbursement for services it provides it does so by submitting Annual Hospital Cost Reports identified as CMS 2252-10. These reports require the hospital to certify, "I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in the cost report were provided in compliance with such laws and regulations."

44. By submitting Forms UB-40, 855(A), and it's Hospital Cost Report for the years 2015, 2016, and 2017, UCMC or UC Health expressly certified that every procedure for which it sought reimbursement complied with Medicare requirements. *United States ex rel Polukoff,* 2018 U.S. App. LEXIS 18539 at ¶27.

45. Furthermore a physician or health care supplier such as UCP when seeking reimbursement for services provided to Medicare patients must submit a CMS 1500 Form to the Medicare contractor. *See United States Ex Rel Hobbs v. Medquest Assoc. Inc.*, 771 F.3d 707, 711 (6th Cir. 2012). The CMS Form reflects the treatment or services provided and identifies the entity that provided them. Tests, supplies, and services are correlated to a series of unique numbers call CPT codes. *Id* at 711. These CPT codes identify the procedures for which UCMC

and UCP are presenting claims seeking reimbursement for the procedures performed at UCMC and UCP. The CMS 1500 Form requires the entity to certify that among other things the services performed by the physicians and identified on the form were medically necessary. *Groat,* 255 F. Supp.3d at 18. That the services billed are medically necessary is a condition of payment - not participation - under the Medicare regulations. *United States Ex Rel Riley*, 355 F.3d at 376 n6.

46. Billing a health care benefit program for medically unnecessary procedures is one way in which a medical care provider can commit health care fraud. *United States v. Med 1st*, 2017 U.S. Dist. LEXIS 177365 at ¶6 (W.D. Ky. Oct. 26, 2017) citing to *United States v. Persaud*, 866 F.3d 371, 380-81 (6th Cir. 2017).

47. As demonstrated herein, UCMC, UCP, and UC Health are presenting claims for reimbursement relating to TAVR procedures that do not meet HHS's NCDs and therefore the medical services for which the claims are being presented are not reasonable and necessary. They constitute false claims for which reimbursement of millions of dollars have been sought and received by UCMC, UCP, and UC Health.

**Transcatheter Aortic Valve Replacement ("TAVR")**

48. UCMC, UCP, and UC Health are submitting false claims relating to Part A (Facility Fees) and Part B (Physician Fees) for treatment provided to Medicare, Medicaid, and Champus patients who are undergoing TAVR procedures.

49. TAVR is a technology used in treating aortic stenosis. A bioprosthetic valve is inserted intravascularly using a catheter and implanted in the orifice of the native aortic valve. The procedure is performed in a cardiac catheterization lab or a hybrid operating room/cardiac catheterization lab with advanced quality imaging and the ability to safely accommodate

complicated cases that may require conversion to an open surgical procedure. The interventional cardiologist and cardiothoracic surgeon jointly participate in the intra-operative technical aspects of TAVR.

50. On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) first issued a NCD covering TAVR under Coverage with Evidence Development (CED) (Attached as Exhibit 2 is Chapter 20.32 of the Medicare National Coverage Determination Manual) ("MNCD Manual"). It has been reissued on a number of occasions with the same volume criteria. The NCD lists criteria for the physician operators and hospitals that must be met prior to beginning a TAVR program or after a TAVR program is established.

**NCD for TAVR Coverage**

51. CMS covers TAVR with the following conditions:

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a FDA-approved indication and when all of the of the following conditions are met

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.

2. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

3. The patient (preoperatively and postoperatively) is under the care of a heart team; a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

A TAVR can only be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site heart valve surgery program,

b. Cardiac catherization or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,

c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),

d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,

e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,

f. Appropriate volume requirements per the applicable qualifications below.

53. There are two sets of qualifications for a health care entity to be entitled to bill for TAVR procedures. The first set outlined below is for a hospital program such as UCMC and heart teams without previous TAVR experience.

54. Before UCMC and UC Health are entitled to bill for a TAVR procedure, they must have had the following:

a. $\geq$ 50 total AVRs (Aortic Valve Replacements) in the previous year prior to TAVR, including $\geq$ 10 high-risk patients, and;

b. $\geq$2 physicians with cardiac surgery privileges, and;

c. $\geq$1000 catheterizations per year, including $\geq$400 percutaneous coronary interventions (PCIs) per year.

55. Additionally, qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

a. Cardiovascular surgeon with:

i. ≥ 100 career AVRs including 10 high-risk patients; or,

ii. ≥ 25 AVRs in one year; or

iii. ≥50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and

b. Interventional cardiologist with:

i. Professional experience with 100 structural heart disease procedures lifetime; or

ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures.

(Attached as Exhibit 2)

**UCMC, UCP, and UC Health have Previously and Continue to Submit Claims for TAVR Procedures Without Meeting the NCD Requirement**

56. In 2014, Satya S. Shreenivas, M.D. joined UCMC, UCP, and UC Health and assumed the role of director of the new Structural Heart Program for the UCMC Heart, Lung & Vascular Institute. (Attached as Exhibit 3) UCMC had constructed a new operating room in order to perform TAVR procedures at a cost of over six million dollars (Exhibit 3).

57. Beginning in the spring of 2015, Dr. Shreenivas was concerned with the issue of whether UCMC and UC Health qualified for Medicare/Medicaid reimbursement for the TAVR procedures under the applicable NCD which were anticipated to be performed at UCMC within the Heart, Lung & Vascular Institute. (Attached as Exhibit 4)

58. On or about April 16, 2015, Dr. Shreenivas forwarded an email string communication between himself and Neil S. Sandler, M.D., who was the Chief Medical Officer for GCS Administrators. By forwarding that email string and pursuant to a subsequent conversation, Dr. Shreenivas informed Dr. Richard Becker that UCMC and UC Health did not qualify under the applicable NCD to bill a government health benefit program for TAVR procedures because UCMC had not performed at least 50 AVRs within the prior year. Dr. Richard Becker was the Chief of the Division of Cardiovascular Health & Disease for the Heart, Lung & Vascular Institute, and the Director of the Heart Lung and Vascular Institute. Dr. Shreenivas asked that the failure of UCMC to achieve the minimum number of AVRs be reviewed by the legal department at UCMC.

59. As previously stated, in order for UCMC, UCP, and UC Health to bill Medicare, Medicaid, TRICARE/Champus for the TAVR procedures, the Medicare NCD required that UCMC and UC Health, as an institution, have performed at least 50 AVRs during the prior year before any patient billings were reimbursable under Medicare. By November 1, 2015, the rolling total of AVR procedures performed at UCMC for the prior year was 26. (Attached as Exhibit 5) On that date, Dr. Shreenivas asked Dr. Louis and Dr. Alan Simeone, cardiac surgeons at UCMC, whether there existed any other patients for whom they had performed AVRs in order to confirm that UCMC had reached the minimal number of 50 AVRs to allow UCMC, UCP, and UC Health to bill a government medical benefit programs for the TAVR procedures. No additional information was received in response to Exhibit 5.

60. On November 16, 2015, UCMC, through its HLVI Operations and Implementation Committee, issued a status report on the Structural Heart Program for TAVRs.

The status report stated that UCMC was ready to begin TAVR procedures within its Structural Heart Program beginning on December 15, 2015. (Attached as Exhibit 6, p. 4) The status report also confirmed that the rolling total for the number of AVRs for the previous year was 26. The first anticipated patient under the UCMC Structural Heart Program was a VA patient with the next three being Medicare patients.

61. Prior to the submission of any billings to a government sponsored benefit program for the TAVR procedures performed at UCMC, Dr. Shreenivas again informed UCMC, UCP, and UC Health that billing for these procedures was unlawful. Specifically, on January 25, 2016, Jamie Hamm, the billing coordinator for UC Health, UCMC, and UCP, wrote to Dr. Shreenivas to indicate that an inpatient account for RT MR04020680 had not yet been billed for TAVR procedure performed on December 14, 2015 in the amount of $167,000 due to Dr. Shreenivas' failure to complete the operating procedure "OP" note. (Attached as Exhibit 7, p. 3)

62. By February 1, 2016, Dr. Shreenivas still had not completed the OP note because he believed billing Medicare for the December 14, 2015 TAVR procedure was illegal. As a result, Dr. William Naber, who was the Medical Director at the UCMC and West Chester Hospital, asked Peter Clayton, the Executive Director for Business Affairs at the University of Cincinnati and UCP, for his assistance in obtaining Dr. Shreenivas' OP note for Patient RT MR04020680 (Exhibit 7, p. 2) On that date, Mr. Clayton ordered Dr. Shreenivas to complete the dictation so that the patient account could be billed to Medicare. (Exhibit 7, p. 1)

63. In response, Dr. Shreenivas informed Peter Clayton and William Naber, that RT MR04020680 could not be billed. (Exhibit 7, p. 1) Dr. Shreenivas believed that billing

Medicare for the TAVR procedure was illegal because UCMC had not met the threshold requirement of 50 AVRs for the prior year under the Medicare NCD.

64. William Naber responded on February 3, 2016.

> I have talked to Craig Cain about this case, he was peripherally aware. We will be billing only Medicare (not the patient) so we still need the dictation to do this properly. Thanks for all of your help clarifying this delicate situation. (Attached as Exhibit 7)

65. On August 25, 2016, Dr. Shreenivas wrote to Rhonda Schlesinger, a billing code manager for UCMC, UCP, and UC Health, inquiring about the billing status for the TAVR patients in which he had performed that procedure.

66. In response, Ms. Schlesinger provided a TAVR case log identifying the payment status for the TAVR billings for all TAVR patients, including those that had been presented to various government programs. (The presentment of claims for TAVR procedures to the United States is outlined in paragraphs 69 and 70)[1]

67. In addition to the foregoing, Relator is aware that Dr. Tim Smith, a former member of UCMC's medical staff and a former employee of UCP, told UCMC and UCP officials that billing government sponsored health care programs for TAVR procedures when the NCD prerequisites had not been met for AVR volume was unlawful. This information was conveyed to Dr. Gregory Rouan, the Chairman of the Department of Internal Medicine for the University of Cincinnati, Peter Clayton, Dr. Richard Becker, and Dr. Charles Hattemer, the Associate Chief of Clinical Affairs at UCMC and a member of UCP.

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[1] The names are redacted in this Complaint, but have been identified through the Medical Record Number and by initials.

68. Because Dr. Shreenivas and Dr. Smith were concerned, in part, about UCMC's, UCP's, and UC Health's unlawful conduct, both ceased their employment with UCP. They began work with The Christ Hospital in 2017.

69. From December 14, 2015 through August 22, 2017, 33 TAVR procedures were performed at UCMC by Dr. Shreenivas and Dr. Imran Arif, both of whom are UCP physicians.[2] Of the 33 TAVRs performed at UCMC, at least 12 were billed to Medicare, CareSource (Ohio Medicaid), and the Veterans Administration-TriCare/Champus. They are:

| Patient | MRN | CPT Code | Date Performed | Date Posted | Inv. No. | Insurance Carrier |
|---|---|---|---|---|---|---|
| RT | 04020680 | 33361-62 | 12/15/15 | 03/17/16 | 40149750 | VA |
| MH | 02091788 | 33361-62 | 01/26/16 | 03/17/16 | 40150690 | CareSource |
| FM | 03591601 | 33361-62 | 02/16/16 | 03/17/16 | 40150481 | VA |
| TH | 02557605 | 33361-62 | 03/08/16 | 03/17/16 | 40150857 | VA |
| LA | 03328402 | 33361-62 | 03/15/16 | 03/17/16 | 40150565 | Medicare |
| MH | 02792037 | 33361-62 | 03/15/16 | 03/17/16 | 40150825 | Medicare |
| JL | 02996829 | 33361-62 | 04/12/16 | 04/15/16 | 40535904 | Medicare |
| DA | 06197170 | 33361-62 | 04/26/16 | 05/05/16 | 40770270 | VA |
| HL | 04425043 | 33361-62 | 06/21/16 | 06/21/16 | 41647283 | VA |
| LA | 03429589 | 33361-62 | 07/26/16 | 08/04/16 | 41767487 | Medicare |
| MH | 04105981 | 33361-62 | 08/09/16 | | 42033245 | Medicare |
| RB | 04096472 | 33361-62 | 08/23/16 | 08/24/16 | | VA |

70. Since August of 2017, 21 additional TAVR procedures have been performed and billed to the United States. They include:

| Patient | Medical Record No. | Date Performed |
|---|---|---|
| WC | 04401180 | 12/05/2017 |
| EM | 02479685 | 02/06/2018 |
| JS | 02250143 | 02/06/2018 |
| RM | 04709580 | 03/06/2018 |
| JK | 06130812 | 03/06/2018 |

[2] Relator has a document produced by UCMC which identifies the 33 patients. In this complaint Relator has identified the patients by their first and last initials.

| | | |
|---|---|---|
| WB | 02460322 | 03/13/2018 |
| RS | 02051445 | 03/13/2018 |
| JB | 06335963 | 04/18/2018 |
| SC | 02926968 | 04/24/2018 |
| JE | 03315974 | 05/08/2018 |
| MW | 02078771 | 05/08/2018 |
| RJ | 03062424 | 05/10/2018 |
| RW | 04754239 | 05/22/2018 |
| RF | 04016327 | 05/29/2018 |
| CH | 06031219 | 05/29/2018 |
| RM | 04006380 | 06/05/2018 |
| LP | 02206028 | 06/12/2018 |
| NC | 02849051 | 06/26/2018 |
| TC | 02162542 | 06/26/2018 |
| JL | 06121610 | 07/10/2018 |
| OM | 02794412 | 07/10/2018 |

**UCMC, UCP, and UC Health Submitted False Claims**

71. The submission of claims by UCMC, UCP, and UC Health identified herein for reimbursement of the expenses incurred for TAVR procedures are false claims.

72. Prior to 2016, UCMC, UCP, and UC Health had submitted various forms to CMS and Medicare. Specifically, in its application to participate in Medicare, UCMC certified in CMS Form 855(A) its compliance with all Medicare laws. Additionally, in its year-end CMS form submission for 2015, 2016 and 2017, it certified that "the services identified in the cost reports were provided in compliance with [the laws and regulations regarding the provision of healthcare services]. Similarly, UCP submitted its CMS 1500 forms and in doing so certified that the medical services, i.e. TAVRs, were medically necessary.

73. Under federal law, a claim presented by UCMC, UCP and/or UC Health for a TAVR procedure must comply with an applicable NCD for it to be considered a reasonable and necessary procedure eligible for reimbursement. Unless the claims submitted by UCMC, UCP,

and UC Health for the TAVR procedures over the period of 2015 to the present met the NCD as set forth in Chapter 20.32 of the MNCD Manual, they cannot be considered to represent medical services which are reasonable and necessary for purposes of obtaining reimbursement from a government sponsored program.

74. Prior to their submission of claims for reimbursement of expenses incurred in performing TAVRs beginning in December 2015, UCMC, UCP and/or UC Health had not met the prerequisite volume of AVRs in the prior year as mandated by the CMS-NCD, and, therefore, any request for reimbursement for medical services relating to the TAVR procedures is not reasonable and necessary under federal law.

75. Notwithstanding those warnings, UCMC, UCP, and UC Health have knowingly continued to violate the FCA by presenting claims to government sponsored medical insurance programs for TAVR procedures in violation of the NCD. By definition, these billings are medical procedures which are not reasonable and necessary under 42 U.S.C. §1395y(a)(1)(A). Accordingly, they constitute false claims.

**Sienter**

76. As set forth herein, from 2015 through 2017 UCMC, UCP, and UC Health were informed that billing for TAVR procedures that did not meet the requirements set forth in the applicable NCD was unlawful.

77. Nevertheless, the Defendants submitted claims to the United States for the reimbursement of expenses incurred in the performance of TAVR procedures while knowing that the presentation of a claim for TAVRs that did not meet the NCD volume requirements was illegal and in violation of federal law.

**Materiality**

78. Under federal law, an express condition of payment for medical procedures performed by Medicare participants is that the procedure is reasonable and necessary.

79. The United States has taken the position that under Medicare a claim is false if it is not reimbursable and a Medicare claim is not reimbursable if the services issued were not medically necessary. (Exhibit 1, pp. 8, 22 citing to 42 U.S.C. §1395y(a)(1)(A)) Thus, if a defendant seeks federal reimbursement for procedures that they knew or had reason to know were not medically necessary, they defrauded the government and should be liable for that fraud. (Exhibit 1, p. 22)

80. The benefit of the bargain between UCMC, UCP, and UC Health, as medical participants in government sponsored health care programs, relates to the requirement that the Defendants will only bill the United States for services and items that are reasonable and necessary and in turn, the United States will only pay for those items consistent with its statutory and regulatory parameters set forth by Congress and CMS. By submitting claims for services that are not defined as reasonable and necessary by the applicable statutory authority, UCMC, UCP, and UC Health have breached the bargain between itselves and the United States, entitling the United States to recoup the amounts previously paid and refusing to make payments on any future TAVR requests.

81. If the United States had known that the Defendants' submissions for TAVR reimbursement were not reasonable or necessary, the United States would not have paid these claims.

**Presentment and Rule 9(b)**

82. Pursuant to paragraphs 69 and 70 of the complaint, Relator has identified the who, what, when, and where of the fraudulent submissions to the United States had been made. For example, Patient RT had a TAVR performed on December 15, 2015, the claim was presented by the Defendants on March 17, 2016 pursuant to invoice number 40149750 and paid by the United States. The CPT Codes for the bill are 33361 and 33362. CPT Code 33361 is a bill for TAVR with prosthetic valve percutaneous femoral artery approach and CPT Code 33362 is a bill for TAVR with prosthetic valve open femoral artery approach. Each of the procedures identify herein satisfies Federal Rule of Civil Procedure 9(b).

**B. The Conduct Of The Defendants Is A Violation Of The False Claims Act, 31 U.S.C. § 3729, Et Al.**

**1. The Actions of UCMC, UCP, and UC Health are A Violation of 31 U.S.C. §3729(a)(1)(A).**

83. Relator realleges the allegations contained in paragraphs 1 through 82 as if fully rewritten herein.

84. From December 14, 2015 to the present, UCMC, UCP, and UC Health have knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, false or fraudulent TAVR claims to the United States Government for payment by federally funded health insurance programs in violation of 31 U.S.C. §3729(a)(1)(A).

85. UCMC, UCP, and UC Health falsely certified that, before presenting a claim for payment from a federally funded health insurance program, they had complied with federal laws which was untrue.

86. The false representations were material to the United States' decision to pay the claims presented by UCMC, UCP, and UC Health. By presenting claims that were in violation of federal laws, they are in violation of the FCA for which the United States seeks reimbursement from UCMC, UCP, and UC Health for three times the amount of money paid by the United States, plus civil penalties.

**2. The Actions of UCMC, UCP, and UC Health are A Violation of 31 U.S.C. §3729(a)(1)(B).**

87. Relator realleges the allegations contained in paragraphs 1 through 86 as if fully rewritten herein.

88. From December 14, 2015 to the present, UCMC, UCP, and UC Health knowingly or in reckless disregard or in deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be used, false or fraudulent records or statements or statements material to a false statement to the United States for the purpose of having a false or fraudulent TAVR claim paid or approved in violation of 31 U.S.C. §3729(a)(1)(B).

89. The representations referred to above were material to the United States' decision to pay the claims presented by UCMC, UCP, and UC Health.

90. The United States was unaware of the falsity of the claims or statements made, or caused to be made by UCMC, UCP, and UC Health, and in reliance of the accuracy of these claims and/or statements, paid for procedures provided to individuals by UCMC, UCP, and UC Health insured by federally funded health insurance programs.

91. By presenting claims that were in violation of the FCA, the United States seeks reimbursement from UCMC, UCP, and UC Health for three times of the amount of the money

paid, plus civil penalties.

### 3. The Actions of UCMC, UCP, and UC Health Are a Violation of 31 U.S.C. §3729(a)(1)(G).

92. Relator realleges the allegations contained in paragraphs 1 through 91 as if fully rewritten herein.

93. 31 U.S.C. § 3729(a)(1)(G) provides that any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the United States, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the United States, has committed a violation of the FCA.

94. The term obligation means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee based or similar relationship, from statute or regulation, or from the retention of any over-payment.

95. UCMC and UC Health have an obligation to submit cost reports under CMS-2552 reconciling payments made to UCMC and UC Health throughout the calendar year. If an overpayment has been made to UCMC and UC Health, it has an obligation to repay the amount to the United States.

96. Due to UCMC's and UC Health's illegal conduct, they have been overpaid by the United States an amount equal to the sums presented for all Part A and TAVR services from December 14, 2015 to the present including the cost of the hospital stay.

97. From 2015 to the present, UCMC and UC Health have failed to identify to the

United States that it has been overpaid the Part A facility and TAVR services performed by UCMC in violation of federal laws.

98. UCMC and UC Health are obligated to report to the United States these overpayments and return the overpayments within 60 days of the date the yearly CMS-2552 reports were due from UCMC and UC Health to their fiscal intermediaries.

99. UCMC's and UC Health's retention of these overpayments is a violation of the FCA and subjects UCMC and UC Health to liability under 31 U.S.C. §3729(a)(1)(A).

**WHEREFORE**, Relator Donald Lynch, M.D., requests that judgment to be entered against UCMC, UCP, and UC Health jointly and severally as follows:

1. UCMC, UCP, and UC Health be enjoined and ordered to cease and desist from submitting or causing the submission of any further false claims;

2. Judgment be entered in the United States' favor against UCMC, UCP, and UC Health in the amount of each and every false or fraudulent claim submitted pursuant to the unlawful scheme described herein and tripled as provided by 31 U.S.C. § 3729(a), and that a civil penalty of not less than $5,500 nor more than $11,000 per claim submitted since December 14, 2015, as provided by 31 U.S.C. § 3729(a) be imposed;

3. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d), including up to 25 percent of the proceeds of the action or settlement of the claim in the event the United States intervenes, or 30 percent of the recovery in the event the United States declines to intervene;

4. That Relator be awarded against UCMC, UCP, and UC Health his costs, including but not limited to court costs, expert fees, and all attorneys fees incurred by Relator in

the prosecution of this suit pursuant to 31 U.S.C. § 3730(d)(1); and

5. For such other and further relief as the Court deems just and proper.

RESPECTFULLY SUBMITTED,

/s/ Mark J. Byrne
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**No. 17-4014**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE TENTH CIRCUIT**

UNITED STATES OF AMERICA ex rel. GERALD POLUKOFF,

Plaintiff-Appellant,

v.

ST. MARK'S HOSPITAL; INTERMOUNTAIN HEALTHCARE, INC.; SHERMAN SORENSEN, M.D.; SORENSEN CARDIOVASCULAR GROUP; INTERMOUNTAIN MEDICAL CENTER; and HCA, INC.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Utah
[District Court Case No. 2:16-CV-304-JNP-EJF (Judge Jill N. Parrish)]

# BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF REVERSAL

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## GLOSSARY

| | |
|---|---|
| CMS | Centers for Medicare and Medicaid Services |
| FCA | False Claims Act |
| PFO | Patent foramen ovale |

## INTEREST OF THE UNITED STATES

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA. The district court committed errors in this case that undermine important government interests in remedying and deterring fraud and protecting patient safety. The court held that a certification that a procedure was medically necessary, for purposes of obtaining federal reimbursement, could not be "false" under the FCA. The court also stated that a corporation could be liable under the FCA only if its "managing agent" possessed the requisite scienter. The United States submits this amicus brief pursuant to Federal Rule of Appellate Procedure 29(a) to explain why both conclusions were incorrect.

## STATEMENT OF ISSUES ADDRESSED

The United States submits this amicus brief to address the following issues:

1. Whether a defendant can be liable under the FCA for certifying that a procedure was medically necessary, knowing that certification to be untrue, for the purpose of obtaining reimbursement from a federal health care program.

2. Whether corporate liability under the FCA requires that a corporation's "managing agent" possess the requisite scienter.

## STATEMENT OF THE CASE

### A. Statutory And Regulatory Background

**1.** The False Claims Act provides that "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is liable to the United States for treble damages and civil penalties. 31 U.S.C. § 3729(a)(1)(A).[1] The statute also imposes liability if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B). The FCA defines "knowingly" to "mean that a person, with respect to information," either "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). No proof of specific intent to defraud is required. *Id.* § 3729(b)(1)(B).

The Attorney General can bring a civil action to remedy a violation of the FCA. 31 U.S.C. § 3730(a). Alternatively, a private person (known as a *qui tam* relator) may bring a civil suit "for the person and for the United States Government." *Id.* § 3730(b)(1). If a relator files a *qui tam* action, the government may intervene and take

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[1] The conduct alleged in this case occurred both before and after Congress amended the FCA through the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-25. *See* Am. Compl. ¶ 2 [Aplt. App. 506-07]. This brief refers only to the current version of the statute, which does not differ from its predecessor in any way relevant to this case.

over the case. *Id.* § 3730(b)(2). If the government declines to intervene, the relator conducts the litigation. *Id.* § 3730(c)(3). The government and the relator divide the monetary proceeds from a *qui tam* suit. *Id.* § 3730(d).

**2.** Medicare, the primary federal health care program at issue in this case, provides federally funded health insurance to eligible elderly and disabled persons. *See* 42 U.S.C. § 1395 *et seq.* In general, after a health care provider performs a covered service for an eligible patient, the Secretary of Health and Human Services, acting through a fiscal intermediary, reimburses the provider in accordance with the Medicare Act and the Secretary's regulations. *See id.* § 1395h; *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 450-51 (1999).

The Medicare Act provides that "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). A provider requesting reimbursement from Medicare must certify that the services at issue were "medically necessary." Centers for Medicare & Medicaid Servs. (CMS), Form 1500, https://go.usa.gov/xNGvF.

The Secretary of Health and Human Services can determine whether an item or service is reimbursable either "by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). If the Secretary chooses the former course, he can issue a "national coverage determination"

that announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). If there is no applicable national coverage determination, a Medicare contractor may issue a "local coverage determination" stating whether an item or service is covered within that contractor's jurisdiction. *Id.* § 1395ff(f)(2)(B).

Where there is no applicable national or local coverage determination, Medicare contractors "make individual claim determinations . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Contractors may reimburse providers for items and services that are "[s]afe and effective," "[n]ot experimental or investigational," and "[a]ppropriate." CMS, *Medicare Program Integrity Manual* § 13.5.1 (2015), https://go.usa.gov/xNGwE (addressing local coverage determinations); *see also id.* § 13.3 (applying these standards to individual claim determinations). One factor relevant to whether an item or service is "[a]ppropriate" is whether it is "[f]urnished in accordance with accepted standards of medical practice." *Id.* § 13.5.1.

**B. Prior Proceedings**

1. Defendants allegedly sought federal reimbursement for medically unnecessary cardiac procedures, including patent foramen ovale (PFO) closures. Am. Compl. ¶ 2 [Aplt. App. 506-07]. Although the federal government has not issued a national coverage determination regarding these procedures, the relator alleges that "[t]here has long been general agreement in the medical community that PFO closure is not medically necessary, except in the limited circumstances where there is a

confirmed diagnosis of a recurrent cryptogenic stroke or" transient ischemic attack. *Id.* ¶ 83 [Aplt. App. 524]. The relator cites industry guidance that assertedly supports his view, *see id.* ¶¶ 83-86 [Aplt. App. 524-25]; alleges that one of the defendant hospitals incorporated a similar standard into its internal policies, *id.* ¶¶ 87-90 [Aplt. App. 525-26]; and claims that Medicare contractors have taken the same position in local medical-review policies, *id.* ¶ 92 [Aplt. App. 526].

Defendant Sherman Sorensen allegedly departed from these standards by performing PFO closures on patients with migraines. Am. Compl. ¶ 137 [Aplt. App. 542-43]. The relator alleges that, because Dr. Sorensen knew "Medicare and Medicaid would not pay for PFO closures to treat migraines," he falsely indicated on patient records that he had performed the procedures based on "confirmed recurrent cryptogenic stroke." *Id.* He also allegedly performed the procedures at a high rate—for example, the relator claims that the Cleveland Clinic performed 37 PFO closures in 2010, while Dr. Sorensen performed 861. *Id.* ¶ 136 [Aplt. App. 542].

The relator asserts that the defendant hospitals encouraged Dr. Sorensen to perform these procedures "despite clear compliance red flags." Am. Compl. ¶ 3 [Aplt. App. 507]. Defendant Intermountain Medical Center allegedly suspended Dr. Sorensen's privileges in 2011, after concluding that he "had performed multiple, medically unnecessary PFO closures." *Id.* ¶ 115 [Aplt. App. 533]. Dr. Sorensen continued to practice at defendant St. Mark's Hospital, where the relator "personally observed Sorensen perform medically unnecessary PFO closures" and at least twice

saw him "*create* a PFO by puncture of the atrial septum in patients who were found to have an intact septum during surgery." *Id.* ¶ 124 [Aplt. App. 536-37]. The relator claims to have notified the CEO of St. Mark's of his concerns, but St. Mark's allegedly continued to allow Dr. Sorensen to perform PFO closures. *Id.* ¶ 133 [Aplt. App. 540-41].

Dr. Sorensen allegedly gave the relator records related to his practice, which the relator contends show specific false claims that defendants submitted to the government. Am. Compl. ¶¶ 141-44 [Aplt. App. 543-606].

2. Defendants moved to dismiss the relator's claims. In the decision under review, the district court granted the motions and dismissed the amended complaint with prejudice.

The district court first addressed whether the relator had pled his claims with the particularity that Federal Rule of Civil Procedure 9(b) requires. *See* Op. 7-15 [Aplt. App. 2515-23].[2] The court explained that Rule 9(b) does not require a relator to allege details regarding particular false invoices; the relator need only "show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." Op. 9-10 [Aplt. App. 2517-18] (emphasis omitted) (quoting *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)).

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[2] The court also considered whether the relator had engaged in forum shopping, *see* Op. 6-7 [Aplt. App. 2514-15], but this brief does not discuss that issue.

Applying that standard, the district court held that the relator had adequately "pled the who, what, when, where, and how of an allegedly fraudulent scheme perpetrated by Dr. Sorensen." Op. 11-12 [Aplt. App. 2519-20]. As for the defendant hospitals, the court explained that the "essence" of the relator's claim was that the hospitals knew "Dr. Sorensen was performing allegedly medically unnecessary procedures in their facilities, but billed the government for costs associated with these procedures anyway." Op. 12-13 [Aplt. App. 2520-21]. The court stated that, because the hospitals "are corporations, this knowledge must be held by a managing agent of either of these corporate entities." Op. 13 [Aplt. App. 2521]. The court held that the relator had stated a claim against St. Mark's, but not against Intermountain. Op. 13-14 [Aplt. App. 2521-22].

The district court rejected all of the relator's claims, however, on the ground that he had not alleged that defendants submitted an "objective[ly] false[]" claim to the government. Op. 15-16 [Aplt. App. 2523-24]. In the court's view, defendants' certifications that the cardiac procedures were medically necessary could not support FCA liability because proof of their falsity would "necessarily rest on evidence of medical opinions and subjective standards of care." Op. 20-21 [Aplt. App. 2528-29]. The district court relied on this Court's statement, in an unpublished opinion, that "the FCA requires proof of an objective falsehood." Op. 16 [Aplt. App. 2524] (quoting *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005) (unpublished)). Although *Morton* expressly declined to hold that a fact

whose "verification . . . relies upon clinical medical judgments" can never "form the basis of an FCA claim," 139 F. App'x at 983, the district court rejected the relator's claims as a matter of law, Op. 18-19 [Aplt. App. 2526-27].

The district court acknowledged the relator's assertion that defendants had departed from industry standards in performing the procedures. Op. 19 [Aplt. App. 2527]. The court rejected the relator's reliance on those standards, however, stating that he wrongly "equate[d] [them] with the medical necessity standard imposed by Medicare." *Id.* The court suggested that defendants could be liable if the government "promulgate[d] a regulation that clarifies the conditions under which it will or will not pay for a PFO closure." Op. 20 [Aplt. App. 2528]. "But in the absence of an objective standard created by the government," the court reasoned, the relator "can only rely upon the subjective and ambiguous 'reasonable and necessary' standard," which the court held could not support liability. *Id.*

## SUMMARY OF ARGUMENT

The FCA applies broadly to "false or fraudulent" claims, 31 U.S.C. § 3729(a)(1)(A), (B), and Congress intended for it to address "all types of fraud, without qualification, that might result in financial loss to the Government," *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). In an FCA case involving eligibility for payment under Medicare, a claim is "false" if it is not reimbursable, and a claim is not reimbursable if the services at issue were not medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A). The district court's contrary holding—that a claim premised

on a knowingly false medical-necessity certification is not "objectively false," and thus cannot be actionable—conflicts with the statute and with decisions of other courts. The ruling also undercuts an essential safeguard against fraud, waste, and abuse and effectively insulates from FCA liability unscrupulous providers who would subject their patients to unnecessary medical procedures for the sake of profit.

Even if FCA liability required an "objectively false" claim, the claims here could meet that standard. By evaluating medical records, witness testimony, and other potential evidence, a jury can make the objective determination whether a medical-necessity certification is true or false. Juries often perform similar exercises in criminal health care fraud cases and malpractice cases, where courts rightly defer to the jury's ability to "weigh the evidence and determine the credibility of witnesses." *Brown v. Presbyterian Healthcare Servs.*, 101 F.3d 1324, 1334 n.9 (10th Cir. 1996). There is no credible basis to treat FCA cases differently. While an FCA defendant might not be liable if he reasonably, but erroneously, believed a procedure was medically necessary, that would be only because he did not act "knowingly," *see* 31 U.S.C. § 3729(a)(1)(A), (B)—not because his claim was reimbursable (*i.e.*, not "false").

The district court also applied an erroneous standard for corporate knowledge, stating that a corporation can be liable only if its "managing agent" possessed the requisite scienter. Op. 13 [Aplt. App. 2521]. That standard departs from basic principles of agency law, and it undermines Congress's intent that the FCA hold responsible corporate officials who "insulate themselves from knowledge of false

claims submitted by lower-level subordinates." S. Rep. No. 99-345, at 7 (1986). A corporation should instead be charged with the knowledge of any of its agents or employees acting within the scope of their authority.

## ARGUMENT

### I. A Certification That A Procedure Was Medically Necessary Can Be "False" Within The Meaning Of The False Claims Act

#### A. The District Court Erroneously Rejected The Relator's Claims For Lack Of An "Objective Falsehood"

1. The FCA imposes civil liability where a defendant knowingly presents a "false or fraudulent claim" to the government. 31 U.S.C. § 3729(a)(1)(A); *see also id.* § 3729(a)(1)(B). A false claim can "take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345, at 9. Congress intended the FCA to "reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968); *see also United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1171 (10th Cir. 2010) (recognizing the FCA's "broad application to all fraudulent attempts to cause the Government to pay out sums of money" (quotation marks omitted)).

"Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005). The federal government will not reimburse a Medicare claim unless the services at issue

were "reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A), and a provider must expressly certify that he or she is seeking reimbursement for "medically necessary" services, CMS, Form 1500, *supra*.

The relator's theory of liability in this case—that defendants sought federal reimbursement for services that they certified were medically necessary, despite knowledge to the contrary—is one that courts have regularly accepted.[3] Indeed, false certifications of medical necessity are of particular concern because they jeopardize patient health and safety. Potential FCA liability provides a critical deterrent to unscrupulous providers who, motivated by profit, might otherwise knowingly subject patients to procedures that would not improve their health and could instead harm them.

The district court nonetheless rejected the relator's claims, concluding that a certification of medical necessity could not support FCA liability because it could not

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[3] *See, e.g.*, *Frazier ex rel. United States v. Iasis Healthcare Corp.*, 392 F. App'x 535, 537 (9th Cir. 2010) (unpublished) (dismissing a claim as inadequately pled but suggesting that the relator could have stated a claim by "provid[ing] reliable indicia that" the defendant "submitted claims for medically unnecessary procedures" (quotation marks omitted)); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (holding that "claims for medically unnecessary treatment are actionable under the FCA" and declining to dismiss a suit where the defendants allegedly "ordered . . . services knowing they were unnecessary"); *see also United States ex rel. Hayward v. SavaSeniorCare, LLC*, No. 11-821, 2016 WL 5395949, at *9-10 (M.D. Tenn. Sept. 27, 2016); *United States v. Robinson*, No. 13-cv-27, 2015 WL 1479396, at *5-6 (E.D. Ky. Mar. 31, 2015); *United States v. Caris Life Scis., Inc.*, No. 10-cv-2237, 2013 WL 11579021, at *3 (N.D. Tex. Oct. 23, 2013); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41-42 (D. Mass. 2000).

be "objectively false." *See* Op. 21 [Aplt. App. 2529]. Citing this Court's opinion in *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980 (10th Cir. 2005) (unpublished), the court stated that, as a matter of law, "[o]pinions, medical judgments, and conclusions about which reasonable minds may differ" could not give rise to FCA liability. Op. 18 [Aplt. App. 2526] (quotation marks omitted). But the FCA applies to all "false or fraudulent" claims, 31 U.S.C. § 3729(a)(1)(A), (B); it does not suggest that only claims that are "objectively" false are actionable. Indeed, the Supreme Court recently rejected a similar effort to narrow the FCA beyond its text, holding that the statute's reference to "false or fraudulent claims" is not limited to claims that involve "misrepresentations about express conditions of payment." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016); *see also* Claire M. Sylvia, *The False Claims Act: Fraud Against the Government* § 4:34 (2016) ("The Supreme Court's decision in *Escobar* confirms that the statute should be read as written and that engrafting nonstatutory requirements onto the statute is unwarranted.").

Although the district court stated that "[o]pinions . . . cannot be false for the purposes of an FCA claim," Op. 18 [Aplt. App. 2526] (quotation marks omitted), it is well established that an opinion *can* be false if the speaker does not believe it or lacks facts to support it. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1330 (2015) (applying that principle in a securities case and noting that it is "not unique to" securities fraud). "In offering an opinion, . . . a speaker is

making the factual statement that *he believes* something." *MHC Mut. Conversion Fund, L.P. v. Sandler O'Neill & Partners, L.P.*, 761 F.3d 1109, 1113 (10th Cir. 2014); *see also* Restatement (Second) of Torts § 539(1) (1977) (a speaker who expresses an opinion implicitly represents that the facts known to him are "not incompatible with his opinion" and "that he knows facts sufficient to justify him in forming it").

That principle applies to FCA claims. Even if "an allegedly false statement constitutes the speaker's opinion," it still "may qualify as a false statement for purposes of the FCA where the speaker knows facts which would preclude such an opinion." *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010) (quotation marks omitted).[4] Here, even if a statement of medical necessity were to be characterized as an "opinion," a person who certified that a procedure was medically necessary while believing it to be unnecessary (or while lacking sufficient basis to make the determination) should be liable. In that circumstance, the district court's objective-falsity framework would suggest the wrong result.

"Judicially-created categories sometimes can help carry out a statute's requirements, but they can also create artificial barriers that obscure and distort those requirements." *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385

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[4] *See also Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047-49 (9th Cir. 2012) (holding that a false estimate can be the basis of FCA liability even if an estimate is an opinion); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999) ("[A]n opinion or estimate carries with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it.").

(1st Cir. 2011) (declining to distinguish between "factually false" and "legally false" claims and "express" and "implied" certifications). The "objective falsity" paradigm does not illuminate the boundaries of FCA liability. A Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary. If defendants sought federal reimbursement for procedures that they knew or had reason to know were not medically necessary, they defrauded the government and should be liable, regardless of whether one might label the falsity of their claims "objective" or "subjective."

2. In any event, even if the FCA did impose liability only for "objectively false" claims, whether the procedures here were reimbursable is objectively verifiable. A Medicare claim is reimbursable only if the services at issue were medically necessary, and an express or implied statement that a procedure was medically necessary is an objective one that can be either true or false. It is also one that a factfinder is well equipped to evaluate, by potential reference to clinical information and other documentation in a medical record, relevant policies and guidance promulgated by the government or other entities, and expert and other witness testimony. *See Medicare Program Integrity Manual* § 13.5.1 (instructing Medicare contractors determining whether an item or service is reimbursable to evaluate, among other things, whether it was "[s]afe and effective," "[n]ot experimental or investigational," "[f]urnished in accordance with accepted standards of medical practice," "[o]ne that meets, but does not exceed, the patient's medical need," and "[a]t least as beneficial as an existing and

available medically appropriate alternative"). Far from being "subjective and ambiguous," Op. 20 [Aplt. App. 2528], Medicare's "reasonable and necessary" standard provides adequate notice of the federal government's expectations in a program that covers thousands of health care services and procedures.

That establishing falsity in a health care fraud case might "rest on evidence of medical opinions and subjective standards of care," Op. 20 [Aplt. App. 2528], does not render an FCA claim incapable of objective evaluation. To the contrary, a jury is fully capable of evaluating, with the aid of expert testimony, whether patient medical records support claims for federal reimbursement. That is true even where the parties might present conflicting medical evidence: "to remove a plaintiff's claims from the jury simply because a difference of opinion among experts [might] exist[] would abrogate the jury's responsibility to weigh the evidence and determine the credibility of witnesses." *Brown v. Presbyterian Healthcare Servs.*, 101 F.3d 1324, 1334 n.9 (10th Cir. 1996) (quotation marks omitted).

Indeed, the need for juries to evaluate competing claims made by medical experts is not limited to the FCA context. In criminal proceedings, this Court has rejected the notion that conflicting medical evidence "per se create[s] a reasonable doubt." *United States v. MacKay*, 715 F.3d 807, 827 (10th Cir. 2013). The Court instead defers to "the jury's resolution of conflicting evidence and its assessment of the credibility of witnesses" in evaluating whether a defendant prescribed a drug "outside the usual course of medical practice and not for a legitimate medical

purpose." *Id.* Similarly, in medical malpractice suits, this Court has recognized that a jury might need to determine which of two experts is more credible regarding the defendant's compliance with the standard of care. *See, e.g.*, *Weese v. Schukman*, 98 F.3d 542, 547-48 (10th Cir. 1996) (reinstating a verdict because it was "within the jury's role as the factfinder to decide that [the plaintiff's] witnesses were not credible and therefore reject their testimony").

Courts have reached similar conclusions in criminal health care fraud cases. The Sixth Circuit recently held that a jury permissibly credited the testimony of government experts to find that a physician had knowingly required his patients to undergo unnecessary cardiac tests and procedures, rejecting his claim that "he was simply an over-protective cardiologist who [was] guilty of nothing more than relying on outdated practice methods." *United States v. Persaud*, No. 16-3105, 2017 WL 2557823, at *7 (6th Cir. June 13, 2017) (motion to publish granted July 7, 2017). The court explained that the defendant had wrongly "ask[ed] th[e] court to re-weigh the expert testimony that was presented at trial"; "the reliability and believability of expert testimony" is instead "exclusively for the jury to decide." *Id.*; *see also United States v. Patel*, 485 F. App'x 702, 709 (5th Cir. 2012) (unpublished) (holding that a jury "was permitted to credit" the testimony of government experts regarding the lack of medical necessity and the existence of false statements over contrary testimony and evidence from the defendant).

This principle applies with full force in FCA cases. As in any other type of litigation, a finder of fact can weigh the evidence and apply the appropriate standard of proof to determine whether a claim was false. Questions involving medical evidence might sometimes be difficult, and there might be FCA cases in which the jury finds that the government or a relator has failed to meet its burden of proof to show that a claim was not reimbursable. That does not mean, however, that the medical-necessity standard gives a jury insufficient guidance to make the relevant determinations. The district court erred in holding that the potential need for "evidence of medical opinions and subjective standards of care," Op. 20 [Aplt. App. 2528], precluded FCA liability as a matter of law.

3. The potential for reasonable minds to disagree about whether a medical procedure was necessary could be relevant to FCA liability—but not because it would preclude a finding of falsity, as the district court believed it would. *See* Op. 16-17 [Aplt. App. 2524-25]. Instead, the potential for a reasonable but erroneous belief that a claim was eligible for payment would go to scienter: to "whether the defendant actually knew or should have known that its conduct violated a regulation." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017).

The FCA imposes liability for the "knowing[]" presentment of a false claim, which includes "actual knowledge," "deliberate ignorance," or "reckless disregard." 31 U.S.C. § 3729(a), (b)(1). If a defendant submitted a claim in good faith, the knowledge requirement would not be met and the defendant would not be liable, even

if the claim was not reimbursable. But that would not mean the claim was not false: as the Supreme Court recently explained, courts should address "concerns about fair notice and open-ended liability . . . through strict enforcement of the Act's materiality and scienter requirements," not by "adopting a circumscribed view of what it means for a claim to be false or fraudulent." *Escobar*, 136 S. Ct. at 2002 (quotation marks omitted); *see also United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir. 1999) ("A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.").

4. The cases on which the district court relied are not to the contrary. Although this Court's unpublished opinion in *Morton* stated that the FCA "requires proof of an objective falsehood," *Morton* expressly declined to hold that a "fact cannot form the basis of an FCA claim" "merely because [its] verification . . . relies upon clinical medical judgments." 139 F. App'x at 982-83; *see also id.* at 983 ("[N]ot all clinical diagnoses and characterizations of medical care are intrinsically ambiguous."). This Court explained that the question is instead whether "the allegedly 'false' statement is susceptible to proof of truth or falsity." *Id.* As this brief explains, a medical-necessity certification is susceptible to proof of truth or falsity. Particularly in light of the Supreme Court's recent decisions in *Escobar* and *Omnicare*, this Court should clarify that the potential for reasonable disagreement about a claim's eligibility

for payment might bear on scienter but does not preclude a finding of falsity, "objective" or otherwise.

Some of the other cases the district court cited are best read to turn on conclusions regarding scienter. *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999), dismissed a claim because the relator had offered "no reason to believe that the City of Green Bay was out to cheat the federal government." Judge Jones's concurring opinion in *United States v. Southland Management Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J., concurring), likewise reasoned that defendants had not "knowingly" presented a false claim because, among other things, there were "legitimate grounds for disagreement over the scope" of the relevant requirements and the defendants had acted "in good faith." Similarly, although *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676-77 (N.D. Miss. 2011), referred to objective falsity, it turned on a conclusion that the defendant had reasonably believed its conduct was permissible.

The district court's reliance on *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996), was also misplaced. As the Ninth Circuit has since made clear, that case addressed an unusual statute and did not broadly limit the types of claims that can be "false or fraudulent." *See Oliver*, 195 F.3d at 463. *Hagood* does not govern falsity in the ordinary case, where it is the defendant's compliance with applicable requirements, "as interpreted by th[e] court," that determines whether he submitted a false claim. *Oliver*, 195 F.3d at 463. Similarly, although *United States ex rel. Wilson v.*

*Kellogg Brown & Root, Inc.*, 525 F.3d 370 (4th Cir. 2008), mentioned the concept of "objective falsehood," it turned on a holding that a relator cannot state a claim merely by alleging that he disagrees with the defendant's interpretation of a contractual provision. *See id.* at 377-78 (contrasting the case with one in which a defendant knowingly submitted inaccurate information to obtain a government contract).[5]

**B. The Relator Adequately Alleged Falsity In This Case**

The relator adequately alleged that the cardiac procedures here were medically unnecessary and that defendants' claims were therefore false. The relator alleged, among other things, that the procedures contravened industry and hospital-level guidelines, Am. Compl. ¶¶ 83-90 [Aplt. App. 524-26]; that Dr. Sorensen performed an exceptionally large number of procedures, *id.* ¶ 93 [Aplt. App. 527]; that other physicians expressed concern, *id.* ¶ 114 [Aplt. App. 533]; that one hospital suspended Dr. Sorensen's privileges because he performed "multiple, medically unnecessary PFO

[5] The other cases the district court cited likewise do not support its conclusions. In *United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006), after considering extensive evidence regarding the necessity of the services at issue, the district court determined that the defendant's practices were "within the range of reasonable medical and scientific judgment" and that there was no "objective gap . . . between what the [d]efendant represented and what the [d]efendant would have stated had the [d]efendant told the truth." *Id.* at 1026-28, 1032-33. The district court here undertook no such inquiry. In any event, *Prabhu* did not override dispositive precedent from its Circuit holding that questions of good faith go to scienter, rather than falsity. *See Oliver*, 195 F.3d at 464. The government has appealed *United States v. AseraCare, Inc.*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015), which acknowledged in any event that "a difference of opinions among treating physicians and medical experts" does not "always defeat falsity." *Id.* at 1381 n.6.

closures," *id.* ¶ 115 [Aplt. App. 533]; and that Dr. Sorensen falsified medical records to conceal his conduct, *id.* ¶ 137 [Aplt. App. 542-43]. Indeed, the district court held that the relator had "adequately [pled] the specifics of a purportedly fraudulent scheme" by Dr. Sorensen "to defraud the government in violation of the FCA." Op. 12 [Aplt. App. 2520]; *see also* Op. 14 [Aplt. App. 2522] (similar conclusion as to one of the hospitals). These allegations, taken together, suffice to state a claim, and the district court erred in rejecting them.

One error merits specific discussion. The relator referred to industry guidelines allegedly stating that, while PFO closure may be appropriate for patients who have suffered strokes, "closure of a PFO for the treatment of migraine headaches is not indicated." Am. Compl. ¶¶ 83-86 [Aplt. App. 524-25]. The district court rejected the relator's reliance on these guidelines, relying on *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011), to conclude that "Medicare does not require compliance with an industry standard as a prerequisite to payment." Op. 19 [Aplt. App. 2527]. In *Chesbrough*, however, the court understood the relators to allege that industry standards were themselves a prerequisite of payment. *See* 655 F.3d at 467-68. Here, the relator is citing industry standards as evidence that defendants violated the statutory and regulatory medical-necessity requirement. While departure from industry practices

might not itself render a claim false, it is evidence that might tend to suggest a procedure was not reasonable and necessary.[6]

In fact, one of the factors the government considers in determining whether a procedure was "reasonable and necessary" is whether it was "[f]urnished in accordance with accepted standards of medical practice." *Medicare Program Integrity Manual* § 13.5.1. Courts likewise refer to industry practices in evaluating FCA claims. *See, e.g., United States ex rel. Todd v. Fidelity Nat'l Fin., Inc.*, No. 12-cv-666, 2015 WL 1297557, at *3 (D. Colo. Mar. 19, 2015) ("[T]he standards of the title industry are relevant to a determination of whether the investigation and FCA claims of [the plaintiff] had a reasonable basis."); *cf. Persaud*, 2017 WL 2557823, at *9 (crediting government witness testimony regarding "the generally accepted threshold" at which cardiac procedures became necessary). A jury evaluating whether procedures were medically necessary might find it probative that a defendant performed the procedures when other members of his profession generally would not do so.

In rejecting reliance on industry guidelines, the district court suggested that a claim for reimbursement could be "false" only if it contravened a federal regulation defining "the conditions under which [the government] will or will not pay for a PFO

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[6] *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), *abrogated on other grounds by Escobar*, 136 S. Ct. 1989, on which the district court also relied in this section of its opinion, expressly acknowledged that a defendant may be liable under the FCA where "a party contends that a particular procedure was deleterious or performed solely for profit." *Id.* at 698.

closure." *See* Op. 19-21 [Aplt. App. 2527-29]. The Secretary of Health and Human Services has broad discretion, however, to make reimbursement decisions either "by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). That discretion would be meaningless if a generally applicable rule were the only way for the government to protect itself against fraud. Issuing national coverage determinations as to every conceivable medical service would also leave no room to consider individual circumstances that might bear on medical necessity (which a jury considering an FCA claim, by contrast, is well equipped to evaluate). Furthermore, it is not clear that forcing the government to issue thousands of national coverage determinations would "help would-be defendants anticipate and prioritize compliance obligations" in any meaningful way. *Escobar*, 136 S. Ct. at 2002. The medical-necessity requirement applies even where the government has not issued a national coverage determination, and a jury can weigh the evidence to decide whether it is knowingly violated.

## II. A Corporation Is Liable For The Acts Of Its Agents

The district court also erroneously stated that a corporation could be liable under the FCA only if its "managing agent" possessed the requisite scienter. Op. 13 [Aplt. App. 2521]. The court cited no authority for that proposition, which disregards basic principles of agency law. "It is well established that a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority." *Western Diversified Servs., Inc. v. Hyundai Motor Am., Inc.*, 427 F.3d 1269, 1276

(10th Cir. 2005); *see also* 3 William Meade Fletcher et al., *Fletcher Cyclopedia of the Law of Corporations* § 790, at 16 (perm. ed., rev. vol. 1999) ("[A] corporation is charged with constructive knowledge . . . of all material facts of which its officer or agent receives notice or acquires knowledge while acting in the course of employment within the scope of his or her authority."); Restatement (Third) of Agency § 5.03 cmt. a (2006) (acknowledging "the general principle that a principal is charged with notice of facts that an agent knows or has reason to know").

There is no reason to depart from these principles in the FCA context. To the contrary, Congress specifically intended that the FCA "hold responsible those corporate officers" who engage in "'ostrich-like' conduct," "insulat[ing] themselves from knowledge of false claims submitted by lower-level subordinates." S. Rep. No. 99-345, at 7. Other courts of appeals have thus held that corporations "may be vicariously liable under the FCA for the misrepresentations of their employees" so long as the relevant employee "is acting within the scope of his or her employment." *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir 2012); *see also United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747-48 (7th Cir. 2013) ("Corporations . . . 'know' what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge."); *United States v. Hangar One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977) (rejecting the notion that a corporation is liable only if the

wrongdoing employee "has a position of substantial responsibility and broad authority").

The district court's error regarding corporate scienter was a fundamental one, but it is not clear whether it affected the outcome in this case. The court concluded that the relator had adequately pled knowledge on the part of one of the defendant hospitals but, as to the other, had failed to identify "who knew what and when they knew it." Op. 13-14 [Aplt. App. 2521-22]. It is not clear whether that conclusion turned on a distinction between the knowledge of "managing agents" and the knowledge of other employees, and the government takes no position as to whether the relator's allegations establish corporate knowledge under the proper standard. This Court should nonetheless correct the district court's misstatements of the falsity and scienter standards and remand the case for further proceedings.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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JULY 2017

## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rules of Appellate Procedure 29(a) and 32(a). This brief contains 6500 words and was prepared in 14-point Garamond, a proportionally spaced font.

*s/ Sarah Carroll*
Sarah Carroll

## CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that (1) all required privacy redactions have been made; (2) any paper copies of this document submitted to the Court are exact copies of the version filed electronically; and (3) the electronic submission was scanned for viruses and found to be virus-free.

*s/ Sarah Carroll*
Sarah Carroll

## CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

*s/ Sarah Carroll*
Sarah Carroll

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 1 (Sections 10 – 80.12)

## Coverage Determinations

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***(Rev. 206, 04-03-18)***

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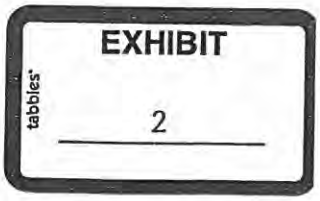

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## Foreword - Purpose for National Coverage Determinations (NCD) Manual

**(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)**

### A. Purpose

The statutory and policy framework within which National Coverage Determinations (NCDs) are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The NCD Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. NCDs have been made on the items addressed in this manual. Decisions that items/services are not covered are generally based on §1862(a)(1) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the authority for denial. Where an item/service is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items/services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item/service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item/service is not mentioned at all in the Centers for Medicare & Medicaid Services (CMS) NCD Manual the Medicare Administrative Contractor (MAC) has the discretion to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings, and general program instructions

The coverage determinations in the manual will be revised based on the most recent medical and other scientific and technical evidence available to CMS.

Other manuals in this system in which coverage-related instructions may be found are:

Pub 100-02 (Benefit Policy);
Pub 100-04 (Claims Processing);
Pub 100-05 (Medicare Secondary Payer); and
Pub 100-08 (Program Integrity)

These manuals usually contain more general coverage descriptions and/or claims processing instructions. There should be no inconsistencies among the instructions in any of these manuals and the NCD Manual pertaining to coverage. If any such inconsistencies are found, bring them to the attention of CMS, Center for Clinical Standards and Quality, Coverage and Analysis Group, Division of Operations and Information Management.

### B. Organization

The NCD Manual is organized by categories, e.g., medical procedures, supplies, diagnostic services. A table of contents is provided at the beginning of the manual

wasn't on the radar then, so I began investigating a connection between stress and hypertension." (http://www.ideafit.com/fitness-library/mind-body-medicine-balanced-approach) The Cardiac Wellness Program is a multi-component intervention program that includes supervised exercise, behavioral interventions, and counseling, and is designed to reduce cardiovascular risk and improve health outcomes.

B. Nationally Covered Indications

Effective for claims with dates of service on and after May 6, 2014, the Benson-Henry Institute Cardiac Wellness Program meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective May 6, 2014, if a specific ICR program is not included on the above-noted list as a Medicare-approved ICR program, it is non-covered.

D. Other

N/A

(This NCD last reviewed May 6, 2014.)

## 20.32 – Transcatheter Aortic Valve Replacement (TAVR)

**(Rev. 147, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)**

### A. General

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

### B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met

   1. The procedure is furnished with a complete aortic valve and implantation

system that has received FDA premarket approval (PMA) for that system's FDA approved indication.

2. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site heart valve surgery program,

b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,

c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),

d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,

e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,

f. Appropriate volume requirements per the applicable qualifications below.

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

The hospital program must have the following:

a. $\geq$ 50 total AVRs in the previous year prior to TAVR, including $\geq$ 10 high-risk patients, and;

b. ≥ 2 physicians with cardiac surgery privileges, and;

c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

a. Cardiovascular surgeon with:

i. ≥ 100 career AVRs including 10 high-risk patients; or,

ii. ≥ 25 AVRs in one year; or,

iii. ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and,

b. Interventional cardiologist with:

i. Professional experience with 100 structural heart disease procedures lifetime; or,

ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and,

c- Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and,

d. Device-specific training as required by the manufacturer.

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

a. ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and,

b. ≥ 2 physicians with cardiac surgery privileges; and,

c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

Qualifications for heart teams with TAVR experience:

The heart team must include:

a. cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:

i. ≥ 20 TAVR procedures in the prior year, or,

ii. ≥ 40 TAVR procedures in the prior 2 years; and,

b. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

i. Stroke;
ii. All cause mortality;
iii. Transient Ischemic Attacks (TIAs);
iv. Major vascular events;
v. Acute kidney injury;
vi. Repeat aortic valve procedures;
vii. Quality of Life (QoL).

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?

- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?

- What is the long term (≥ 5 year) durability of the device?

- What are the long term (≥ 5 year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following.

1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:

   - What is the incidence of stroke?
   - What is the rate of all cause mortality?
   - What is the incidence of transient ischemic attacks (TIAs)?
   - What is the incidence of major vascular events?
   - What is the incidence of acute kidney injury?
   - What is the incidence of repeat aortic valve procedures?

3. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

   a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

   b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

   c. The research study does not unjustifiably duplicate existing studies.

   d. The research study design is appropriate to answer the research question being asked in the study.

   e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56. In particular, the informed consent includes a straightforward explanation of the reported increased risks of stroke and vascular complications that have been published for TAVR.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed as Medicare coverage requirements.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these

populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

4. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TAVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. **Nationally Non-Covered Indications**

TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

D. **Other**

NA

(This NCD last reviewed May 2012.)

## 20.33 - Transcatheter Mitral Valve Repair (TMVR)

**(Rev. 178, Issued: 12-05-14, Effective: 08-07-14, Implementation: 04-06-15)**

**A. General**

UNIVERSITY OF CINCINNATI MEDICAL CENTER
Cardiovascular Insights
A Clinical, Academic, and Research, Peer-to-Peer Resource
UC Health



# Transcatheter Aortic Valve Replacement (TAVR) Program



An unusually large patient cohort and state-of-the-art medical facilities have expedited rapid growth of the Transcatheter Aortic Valve Replacement (TAVR) Program at the University of Cincinnati Medical Center.

As with many other cardiac diseases, such as coronary blockages and arrhythmias, valvular heart disease is now increasingly being treated in a minimally-invasive manner. This is especially important because surgical aortic valve replacement is currently the main treatment for severe aortic stenosis (AS) patients - without surgery, the three-year survival rate is estimated at less than 30%, and 33% of all severe AS patients over the age of 75 are declined for surgery.[1] Despite the increasing implementation and success of TAVR, however, it is not yet widely practiced outside of academic medical centers.

With a large population of untreated aortic valve stenosis patients, University of Cincinnati Medical Center is positioned for rapid growth in this groundbreaking area, and has begun its own TAVR program under the guidance of Satya S. Shreenivas, MD, who joined the UC Heart, Lung and Vascular Institute in 2014 to take on the role of directing the new structural heart program. He says, "What attracted me is that there is an unusually large number of patients at this facility with untreated moderate-to-severe aortic stenosis. The need here is incredible, and I anticipate that we will grow rapidly to meet that demand." He points out that in cases of severe, inoperable AS, the five-year survival rate is just 3%. Offering these patients advanced treatment has revolutionized their care.

In determining the severity of aortic stenosis (AS), clinicians often use guidelines such as those shown below. However, there are cases in which the numbers don't correlate - a high mean pressure gradient may be associated with a very small aortic valve area, or the reverse. In such cases, it is important for physicians to remember that multiple factors affect an AS diagnosis. Particular values can be caused by other cardiac conditions or patients could be suffering from a condition known as "low-gradient AS," which is associated with very poor prognoses if untreated.

**Aortic Stenosis severity. Image courtesy of Satya Shreenivas, MD.**

AS SEVERITY

| Severity | Mean Gradient | Aortic valve area |
|---|---|---|
| Mild | < 20 mm Hg | > 1.5 cm |
| Moderate | 20-40 mm Hg | 1.0 – 1.5 cm |
| Severe | > 40 mm Hg | < 1.0 cm |

Shreenivas and his colleagues have recently expanded their ability to offer multiple cardiovascular procedures, including TAVR, in their new operating room, which has been built at a cost of $6 million.[2]

University of Cincinnati Medical Center

Contact Us

Newest Articles

Radiofrequency Catheter Ablation in Heart Failure Patients with Atrial Fibrillation More Effective than Medication
January 5, 2018
#afib, #Atrialfibrillation, #heartfailure, #Radiofrequencycatheterablation

Sanghvi Center for Advanced Cardiovascular Imaging Opens
January 5, 2018
#andrewcrean, #imagingcenter

UC Medical Center Researchers Advancing Precision Medicine
January 4, 2018
#hypertrophiccardiomyopathy, #precisionmedicine, #Sadayappan

Multi-Specialty Team Approach Most Effective for Adults with Congenital Heart Disease
January 4, 2018
#ACHD, #adultcongenitalheartdisease, #costea, #crean

A Genetic Variant Can Predispose South Asians to Hypertrophic Cardiomyopathy
February 27, 2017
#geneticvariant, #hypertrophiccardiomyopathy, #myosinbindingproteinC, #Sadayappan

Events

EXHIBIT
tabbies
3

This state-of-the-art hybrid operating room includes $2.6 million in equipment and advanced medical imaging devices.[2] Shreenivas anticipates that this hybrid OR will be the site of many TAVR procedures in the future, as the hospital's program, fueled by its large aortic stenosis patient cohort, continues to grow.

References: 1. Spaccarotella C, Mongiardo A, Indolfi C. Pathophysiology of aortic stenosis and approach to treatment with percutaneous valve implantation. Circ J. 2011;75(1):11-19.
2. http://www.bizjournals.com/cincinnati/news/2015/06/16/cincinnati-hospital-unveils-6m-operating-room.html. Accessed June 25, 2015.

Satya S. Shreenivas, MD
Assistant Professor of Clinical Medicine
Department of Internal Medicine
Division of Cardiovascular Health and Disease
Director, Center for Structural and Adult Congenital Heart Disease
University of Cincinnati Heart, Lung and Vascular Institute

(513) 558-3344
shreensa@ucmail.uc.edu

Posted in Articles

**From:** Becker, Richard (beckerrc) BECKERRC@ucmail.uc.edu
**Subject:** RE: CMS decision memo on TAVR
**Date:** April 16, 2015 at 10:50 AM
**To:** Shreenivas, Satya (shreensa) shreensa@ucmail.uc.edu
**Cc:** Stalica, Lawrence (stalicle) stalicle@ucmail.uc.edu

Thank you Satya. Yes, lets plan to talk in the coming week.
Larry should join us.

Regards;

Richard C. Becker, MD
Mabel Stonehill Endowed Professor of Medicine
Chief, Division of Cardiovascular Health and Disease
Director and Physician-in –Chief
Heart, Lung and Vascular Institute
University of Cincinnati College of Medicine
Director, Cardiovascular Services
UC Health
513.558.4332
Fx 513.558.2884

**From:** Shreenivas, Satya (shreensa)
**Sent:** Thursday, April 16, 2015 10:42 AM
**To:** Becker, Richard (beckerrc)
**Subject:** Fwd: CMS decision memo on TAVR

Dr. Becker,

This is the email from Neil Sandler from CMS. The attached CMS decision memo is exhaustive. The main points of focus are the table on page 31 and the public comments and CMS responses on pages 43 and 44.

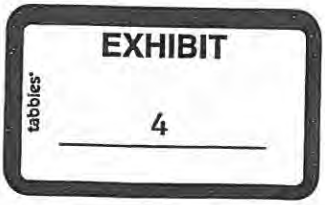
I will schedule another call with Dr. Sandler to further discuss this document.

Perhaps we should meet and talk about this and then consider getting this reviewed by our legal/financial department.

Satya

Begin forwarded message:

**From:** <NEIL.SANDLER@cgsadmin.com>
**To:** <shreensa@ucmail.uc.edu>
**Subject: RE: Thank you**
**Date:** April 6, 2015 at 1:57:28 PM EDT



Date: April 6, 2015 at 1:37:28 PM EDT

Hello Satya

I have been looking at several avenues to try and answer your question regarding the definition of TAVR experience. I will spare you a long diatribe about the various dead ends and focus on something that may provide some guidance. I've attached the decision memo for TAVR. It is quite long. If you have not read it, no need to read it in its entirety. Rather please take a look at table 1 which begins on page 31 of the pdf. Also, immediately below this table there is a section (Section 7) for public comments. On page 43 of the pdf, there is a sub section for institutional requirements in Section 7. These are the two areas I think may have some information of value, but quite frankly, I found the table most interesting. Once you have had an opportunity to review this information, I suggest we schedule a brief call to discuss this to see if we come to the same conclusion.

I appreciate your patience regarding this inquiry.

Regards

Neil

Neil S. Sandler, MD
Chief Medical Officer, J15 A/B MAC
CGS Administrators
Two Vantage Way, Nashville, TN 37228
email: neil.sandler@cgsadmin.com | voice: 615.660.5326| fax: 803.736-2716



-----Original Message-----
From: Shreenivas, Satya (shreensa) [mailto:shreensa@ucmail.uc.edu]
Sent: Tuesday, March 24, 2015 4:34 PM
To: NEIL SANDLER
Subject: Thank you

Dr. Sandler,

Thank you very much for taking the time to talk with me. You have been a tremendous help and it has been a pleasure.

Our question is:

How do you define a program with experience? If we can be considered a program with experience we only have to meet the 20 surgical AVR requirement (which we do). For example, if we did 1-5 TAVR cases for patients that had private insurance or if we did 1-5 cases without requesting reimbursement from Medicare, would that be enough to qualify as a program with experience and could we then qualify as an experienced program?

When the NCD was first released, the only way a program could get experience was if they had been part of a clinical trial since the device was not FDA approved. Since then, it is a FDA approved device and private insurance companies are paying for the procedure. Now, a program could get experience and not be part of a trial. I don't think anyone has done this because 1) most patients in this age range > 65 years old are covered by Medicare and 2) not many programs are willing to do cases for free to gain experience.

Any help you could provide would be of immense help.

Sincerely,

Satya Shreenivas

**From:** Shreenivas, Satya (shreensa) shreensa@ucmail.uc.edu
**Subject:** Aortic valve replacements/timing of tavr program
**Date:** November 1, 2015 at 10:51 AM
**To:** Louis Louis louisilb@UCMAIL.UC.EDU, Alan Simeone SIMEONAA@ucmail.uc.edu

Louis and Alan,

We would like to start doing TAVRs soon. A large part of that is making sure we have the surgical aortic valve replacement volume to be able to start the program.

I have listed the data I have so far for the last 2 years. My question to both of you:

1) Could you give me a rough idea of number of cases you might have for AVR in the next 1-2 months — I have sent over two patients in the last few weeks: Christina Wallace and Gary Kolb. I am not sure if there are other patients (i.e. endocarditis patients we are waiting on for antibiotics etc.).

| | 2014 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Jan | Feb | Mar | Apr | May | Jun | July | Aug | Sept | Oct | Nov | Dec |
| Case/Month | | 2 | 0 | 1 | 3 | 3 | 2 | 4 | 0 | 1 | 2 | 3 | 1 |
| Rolling total | | 2 | 2 | 3 | 6 | 9 | 11 | 15 | 15 | 16 | 18 | 21 | 22 |
| All total | | 2 | 2 | 3 | 6 | 9 | 11 | 15 | 15 | 16 | 18 | 21 | 22 |
| | 2015 | | | | | | | | | | | |
| | Jan | Feb | Mar | Apr | May | June | July | August | September | October | November | December |
| Case/month | | 1 | 0 | 5 | 3 | 2 | 2 | 4 | 1 | 2 | | |
| Rolling Total | | 21 | 21 | 25 | 25 | 24 | 24 | 24 | 25 | 26 | | |
| All total | | 23 | 23 | 28 | 31 | 33 | 35 | 39 | 40 | 42 | | |

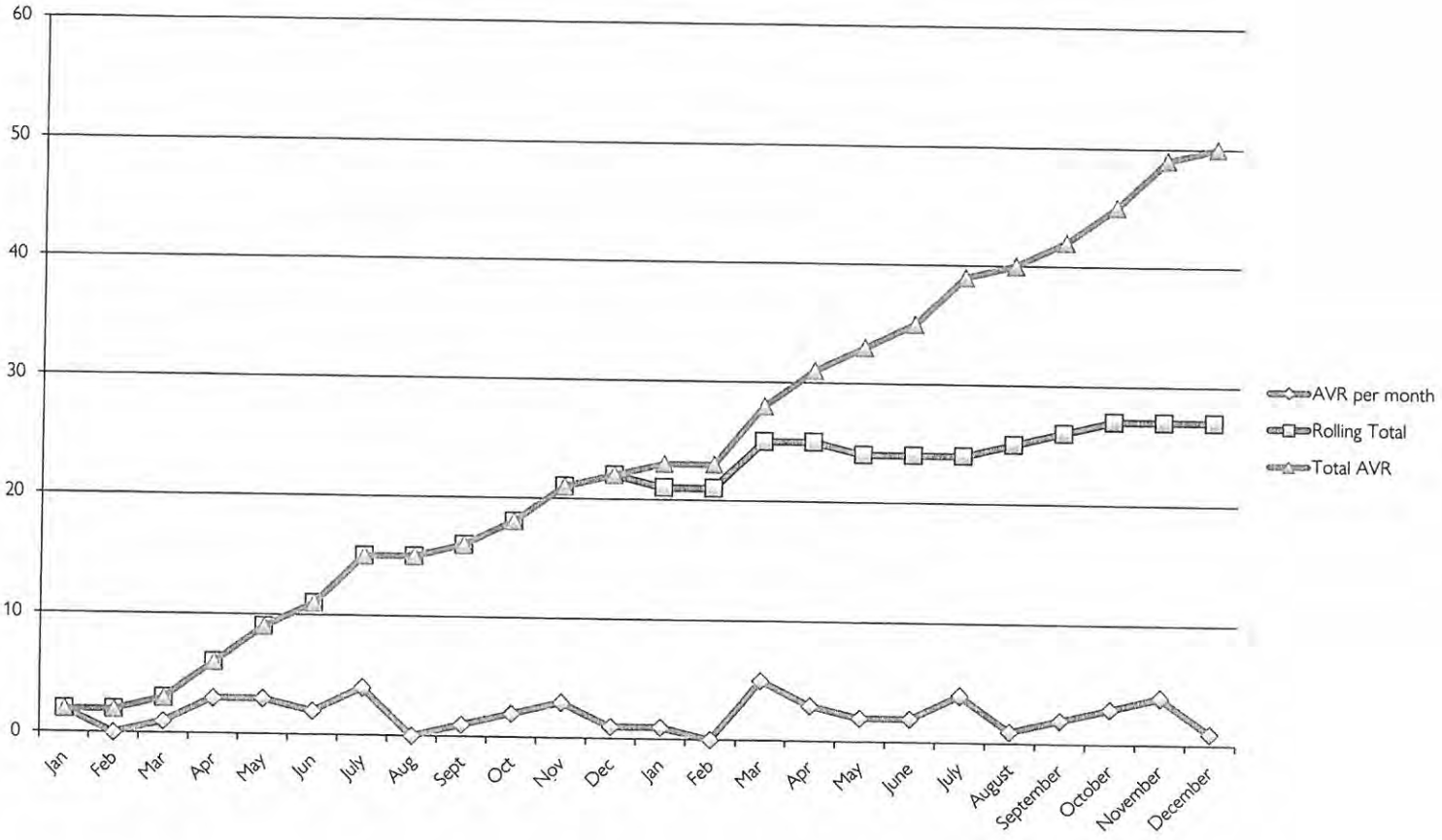
# Structural Heart Program

## HLVI Operations and implementation Committee

November 16, 2015

# AVR VOLUME JAN 2014-PRESENT

- 11/2015 and 12/2015 are predicted



# CALENDAR


- One month from today we will do the first TAVR at UC
- Want to make sure everyone is on board with plan/schedule

# CALENDAR

## December 2015

| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 |
| 6 | 7 Valve Meeting | 8 Anesthesia Clinic Visit | 9 Dry Run #2 (if needed) | 10 | 11 | 12 |
| 13 | 14 Valve Meeting | 15 TAVR | 16 | 17 | 18 Debrief | 19 |
| 20 | 21 | 22 | 23 | 24 | 25 | 26 |
| 27 | 28 | 29 | 30 | 31 | | |

Notes:

Key Dates:

-- November 20 (staff training)

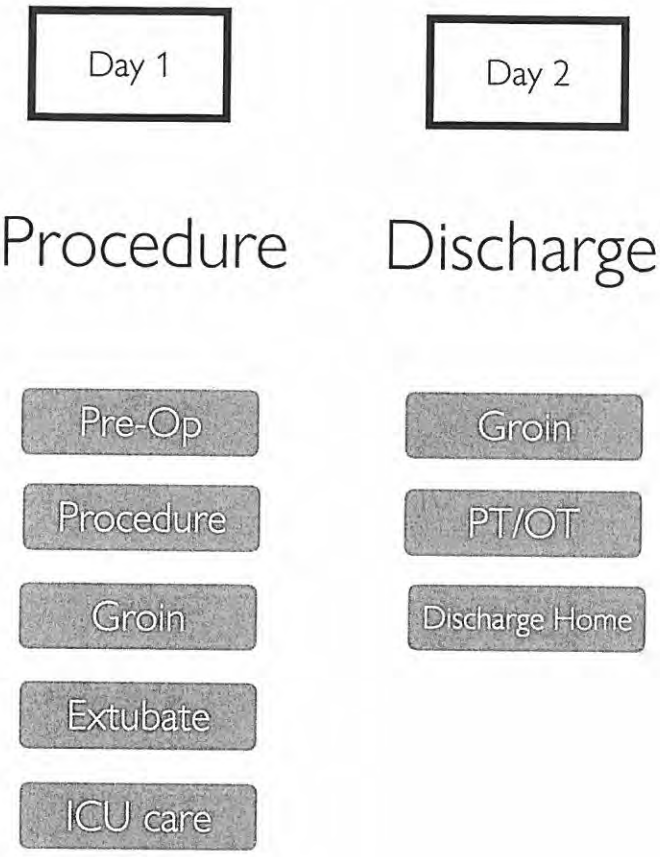
-- Nov 24 (Dry Run #1)

-- December 15 (First Case)

# TAVR Patients

- First 5 patients – all 5 will be presented at 11/23/15 conference
- First Case is VA patient – workup complete
- Second case was supposed to be VA patient –referred by VA to Christ 2 weeks ago.
- Next 3 are Medicare patients (based on severity of symptoms)

# Hospital Course



# Structural Heart Program

- Between now and End of Year:
  - Product Purchase (deadline: _____)
  - TVT Registry (deadline: _____)
  - Coordinator Hire (deadline: _____)

From: **Naber, William (naberwj)** naberwj@UCMAIL.UC.EDU
Subject: RE: Inpatient accounts being held for operative report
Date: February 3, 2016 at 9:11 PM
To: Shreenivas, Satya (shreensa) shreensa@ucmail.uc.edu, Clayton, Peter (claytopr) claytopr@UCMAIL.UC.EDU

Satya and Peter

I have talked to Craig Cain about this case, he was peripherally aware. We will be billing only Medicare (not the patient) so we still need the dictation to do this properly. Thanks for all of your help clarifying this delicate situation.

Thanks--Bill

William J. Naber MD JD
Medical Staff Past President West Chester Hospital 2014-2015
Medical Director UR/CM/CDI UC Medical Center and West Chester Hospital
Associate Professor, Department of Emergency Medicine
University of Cincinnati College of Medicine
Cell: 513-600-4749



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**From:** Shreenivas, Satya (shreensa)
**Sent:** Monday, February 01, 2016 5:26 PM
**To:** Clayton, Peter (claytopr); Naber, William (naberwj)
**Subject:** Re: Inpatient accounts being held for operative report

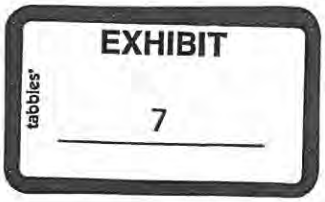
This cannot be billed. Please call me to discuss. Cell:267-226-9211

Satya

Sent from my iPhone

On Feb 1, 2016, at 5:06 PM, Clayton, Peter (claytopr) <claytopr@UCMAIL.UC.EDU> wrote:

> Dr. Shreenivas,
> Please complete your dictation on Roy Tomlin or advise on difficulties. Thanks.
>
> Peter J. Clayton
> Executive Director, Business Affairs
> Department of Internal Medicine
> University of Cincinnati/UC Physicians
> 513.558.3003
>
> **From:** Naber, William (naberwj)
> **Sent:** Monday, February 01, 2016 4:55 PM
> **To:** UCH-Hamm, Jaime (Jaime.Hamm) <Jaime.Hamm@UCHealth.com>
> **Cc:** Clayton, Peter (claytopr) <claytopr@UCMAIL.UC.EDU>



**Subject:** RE: Inpatient accounts being held for operative report

Peter

Can you help with the dictation below please?

Thanks--Bill

William J. Naber MD JD
Medical Staff Past President West Chester Hospital 2014-2015
Medical Director UR/CM/CDI UC Medical Center and West Chester Hospital
Associate Professor, Department of Emergency Medicine
University of Cincinnati College of Medicine
Cell: 513-600-4749

---

**From:** Hamm, Jaime [mailto:Jaime.Hamm@UCHealth.com]
**Sent:** Monday, February 01, 2016 3:05 PM
**To:** Naber, William (naberwj)
**Subject:** RE: Inpatient accounts being held for operative report

As of today I'm still missing the following from Dr. Shreenivas

04020680
Procedure: 12/14/2015 TAVR
Surgeon: Satya Sanatan Shreenivas
$167k

**Jaime M Hamm, RHIT**
Coding Mgr., Corporate Coding Services
513-585-7544
Jaime.hamm@uchealth.com
<image001.png>

---

**From:** William Naber [mailto:naberwj@UCMAIL.UC.EDU]
**Sent:** Monday, January 25, 2016 4:28 PM
**To:** Hamm, Jaime
**Subject:** Re: Inpatient accounts being held for operative report

William J Naber MD JD
513-600-4749
Sent from my I Phone

On Jan 25, 2016, at 3:35 PM, Hamm, Jaime <Jaime.Hamm@UCHealth.com> wrote:

Hi Tal,

The following are IP accounts holding for an OP note and I believe all of these surgeons fall under you (I'm still learning ☺).

I appreciate your help. Thank you

06095269
Procedure: 12/22/2015 Tracheostomy report
Surgeon: Julian Guitron-Roig, MD
$725k

02875031
Procedure: 01/08/2016 Right Heart Cath
Surgeon: Charles R Hattemer
$27k

02140893
Procedure: 12/08/2015 AAA REPAIR, FEMORAL-FEMORAL GRAFT
Surgeon: George H Meier
$177k

04210729
Procedure: 1/04/2016 ORIF left femur/tibia
Surgeon: Frank Roman Avilucea
$602k

04020680
Procedure: 12/14/2015 TAVR
Surgeon: Satya Sanatan Shreenivas
$167k

**Jaime M Hamm, RHIT**
Coding Mgr., Corporate Coding Services
513-585-7544
Jaime.hamm@uchealth.com